REMARKS

Responsive to the Office Action dated December 5, 2002, (hereinafter "the Office Action"), amendments have been made to claims 1, 11-12, 20-21, 23-24 and 26. Claims 10 and 13-19 have been canceled. Upon entry of this amendment, claims 1-9, 11-12, 20-26 and 28-35 will remain pending in the present application.

The Personal Interview

The applicant would like to thank the Examiner for the courteous personal interview which was conducted on March 8, 2004. At the interview, claims 1 and 26 were discussed in light of the cited prior art, the objection to the specification, and the rejection under 35 U.S.C. §112. The applicant proposed the amendment to the specification detailed above to overcome the objection to the specification. The applicant proposed the amendment to claim 26 deleting the text, "...step of conforming the flexible substrate to an area of the treatment zone is accomplished by..." and inserting "is" to overcome the rejection under 35 U.S.C. §112. The Examiner appeared favorably disposed to accepting these amendments and withdrawing the objection and rejection.

The applicant also proposed amendment of either or both of claims 1 and 26 to require that the foil sheet, located adjacent the stent, is not attached to the stent during delivery of the stent to a treatment area. The applicant pointed out that the Tam et al. and Park et al. references both teach attachment of the radioactive material to the stent for delivery of the stent to the treatment area. The Examiner appeared favorably disposed to entry of the amendment in the context of method claim 26, but raised the concern that, in the context of claim 1, this type of limitation could potentially be interpreted as an intended use limitation. Agreement was not reached on the patentability of claims 1 and 26 at the interview.

Co-pending U.S. Patent Applications

The applicant would like to call to the attention of the Examiner the existence of the following co-pending U.S. patent applications for the Examiner's consideration:

A. U.S. Patent Application no. 10/649,529, filed on August 27, 2003.

B. U.S. Patent Application no. 09/858,816, filed on May 16, 2001.

C. U.S. Patent Application no. 09/858,366, filed on May 16, 2001.

D. U.S. Patent Application no. 10/010,250, filed on November 7, 2001.

E. U.S. Patent Application no. 10/342,536, filed on January 15, 2003.

F. U.S. Patent Application no. 10/718,950, filed on November 21, 2003.

The Office Action

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter, namely, the mechanical attachment of adhesives and suturing. The specification has been amended, in accordance with the proposal made at the personal interview of March 8, 2004, to overcome this objection. Basis for the amendment is found in original claims 21-22 of the application. Favorable consideration and withdrawal of the objection is requested.

Claims 26 and 28-35 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite on the basis that it is unclear whether the insertion device referenced in line 10 of claim 26 is the same insertion device referenced in line 4 of claim 26. Claim 26 has been amended, in accordance with the proposal made at the personal interview of March 8, 2004, to overcome this rejection and clarify that the insertion device referenced in line 10 of claim 26 is the same as the insertion device referenced in line 4, of claim 26. Favorable consideration and withdrawal of the rejection is requested.

Claims 1-26 and 28-35 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent no. 6,262,320 (Tam et al.). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

The present invention, as claimed in claim 1, differs from the device set forth in Tam et al. in that Applicant's invention requires two distinct, unattached structural elements, namely, a stent and a foil sheet formed into a coil comprising a radioactive material and located adjacent to the stent. Tam et al. describes only a radioactive stent and therefore Tam et al.'s device lacks one of the two structural elements of applicant's claimed invention, namely, a flexible sheet containing radioactive material formed into a coil. Alternatively, Tam et al. discloses a flexible sheet containing radioactive material formed into a coil but, in this case, Tam et al. lacks a disclosure of the other structural element of the applicant's claimed invention, namely the stent.

In order to address the examiner's concerns regarding the word, "separate," claim 1 has been amended to expressly recite that the flexible foil sheet formed into a coil is not attached to the stent in order to more clearly distinguish over Tam et al. Tam et al. does not disclose a stent used in combination with a flexible foil sheet containing radioactive material formed into a coil, wherein the flexible foil sheet is not attached to the stent.

Applicant notes that the presently claimed structure provides many advantages over the radioactive stent of Tam et al.. For example, radioactive sheets are more economically manufactured than radioactive stents. Also, the radioactive stents described by Tam et al. must be produced in different sizes to fit the vessel requiring support; applicant's invention, however, can be conveniently trimmed to the necessary size at the time of use and can be used with non-radioactive stents that are already in inventory. These and other advantages of applicant's invention specifically result from the claimed two-element structure.

Favorable consideration and withdrawal of the rejection of claim 1, and dependent claims 2-9, 11-12 and 20-25, which depend from claim 1, under 35 U.S.C. §102(e), is requested for at least this reason.

With respect to independent claim 26, claim 26 has been amended to require that the flexible substrate not be attached to an insertion device selected from a stent and an expandable catheter, when the flexible substrate is inserted into the body. In the case of the Tam et al. reference, the radioactive material is delivered as a coating on the stent and thus is attached to the stent at the time of insertion into the body. Thus, this element of claim 26, as amended, is not taught or suggested by Tam et al.

In addition, although Tam et al. discloses that the stent can be inserted by a catheter insertion device, the catheter of Tam et al. does not expand radially to conform a flexible substrate to the treatment zone as is also required by claim 26 of the present application. Thus, both the structure and the steps in amended claim 26 include elements that do not appear in Tam et al.. Accordingly, claim 26 as amended is also believed to be novel over the method described in Tam et al..

The Examiner relied on the following quotation from Tam et al. in the Final Rejection,

> The term 'coating' is intended to cover generically any form of material which is adhered to or deposited on or adjacent the surface of the stent, such as a jacket or thin film...

See col. 20, lines 19-22 of Tam et al.. This quotation from Tam et al. makes it clear that Tam et al. does not contemplate a separate insertion device and flexible sheet as in the present invention since the coating must be "adhered to or deposited on or adjacent the surface of the stent." The use of the terms, "adhered to" and "deposited on" make it clear that the coating becomes part of the stent and is not part of a separate device as in the present invention.

A review of other portions of the Tam et al. reference show that the reference in Tam et al. to a coating "deposited adjacent the surface of the stent" is meant to cover the embodiment wherein the stent is first provided with a "tie layer" and then the radioactive coating is deposited on the "tie layer." See e.g. col. 29, lines 14-47 of Tam et al.. The "tie layer" of Tam et al. is provided to improve the adherence of the radioactive material to the stent. Thus, the reference to depositing a coating "adjacent the surface of the stent" in Tam et al. still refers to a device wherein the stent and radioactive coating are formed integrally and not as two separate elements as in the present invention.

The integral nature of the Tam et al. device is confirmed by the fact that Tam et al. does not describe any embodiments where the stent and radioactive material are two separate devices and by the following statement of one of the advantages of the Tam et al. device found at col. 26, lines 63-66 of Tam et al.:

> Another advantage of the present invention is that the radioisotopes are held by strong atomic-level bonding interactions, and which are highly resistant to leaching or release under physiological conditions.

The discussion in Tam et al. of a "tie layer" and the further discussion in Tam et al. at col. 31, line 48 to col. 32, line 51 of the provision of an outer coating layer on the stent to prevent radioactive material from separating from the stent during use, highlights another advantage of the present invention. Specifically, since the radioactive material of the present invention is provided with a separate flexible sheet, the skilled person need not worry about the Tam et al. problem of finding a way to acceptably adhere the radioactive material to the stent material. Rather, in the present invention, the radioactive material is not adhered to the stent material and thus this problem is eliminated. Instead, the skilled person can choose the material used in the flexible sheet, independent of what material is used to make the stent, in order to avoid problems with adherence of the radioactive material.

Also, the reference at col. 20, lines 19-22 of Tam et al. to a "thin film or jacket" is a reference to a thicker coating as is clear from the fact that these embodiments are given as examples of a coating at col. 20, lines 19-22 and from the statement at col. 32, lines 9-13 of Tam et al. which reads as follows:

> In an alternative embodiment, the coating may take the form of a relatively thicker cover such as a film or jacket, such as having a thickness measured in ten thousandths or one thousandths of an inch or greater.

This quotation from Tam et al. confirms that the reference to a "film or jacket" is just a reference to a thicker coating.

Favorable consideration and withdrawal of the rejection under 35 U.S.C. §102(e) of claim 26, and claims 28-35 which depend from claim 26, for at least this reason, is requested. In conclusion, all claims are considered to be novel in view of Tam et al. for the reasons discussed above. In addition, all claims are considered to be inventive over Tam et al. since Tam et al. does not teach or suggest the features listed above which render the claims novel over Tam et al., nor is there any motivation to modify the device or method of Tam et al. to arrive at the present invention as claimed in the pending claims. Moreover, all claims are considered inventive on the basis of the several advantages described above, which are provided by the presently claimed device, relative to the device of Tam et al.

Claims 1-26 and 28-25 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tam et al. in view of U.S. Patent no. 6,152,869 (Park et al.). Favorable consideration and withdrawal of the rejection in view applicant's amendments is requested.

The Examiner has taken the position that, at least during the manufacturing process, the Park et al. device includes a stent and a separate, unattached sleeve 7 containing radioactive material, relying on figure 2 and col. 5, lines 47-57 of Park et al. However, the Examiner admits that this separate sleeve 7 of the Park et al. device is later attached to the stent prior to delivery of the stent into the body of a patient.

Thus, with respect to method claims 26 and 28-35, as amended, the combination of Tam et al. and Park et al. lacks an element of the invention, as claimed, namely the insertion of a combination of an insertion device such as a stent, and a flexible sheet of radioactive material which is not attached to the insertion device, into the body. Accordingly, since this element of claims 26 and 28-35, as amended, is lacking from both Tam et al. and Park et al. contains this teaching, it is considered that the combination of

Tam et al. and Park et al. do not make out a case of *prima facie* obviousness. According to M.P.E.P. § 2143,

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. **Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.**
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. [*Citation omitted, emphasis added*]

Accordingly, for at least these reasons, favorable consideration and withdrawal of the rejection of claims 26 and 28-35, under 35 U.S.C. §103(a) over a combination of Tam et al. and Park et al. is requested.

With respect to claims 1-9, 11-12 and 20-25, by virtue of the amendments to claim 1, each of these claims now requires a combination of a stent, and a flexible foil sheet containing a radioactive material which is formed into a coil and is not attached to the stent. Thus, in order to arrive at the subject matter of claim 1 starting with the disclosure of Tam et al., the coiled stent of Tam et al. must be modified into two separate elements, a stent, and an unattached, coiled flexible foil sheet containing a radioactive material.

The Examiner relies on the teaching of Park et al. that the radioactive sleeve 7 may be first formed of a separate member (figure 2) which is later attached to the stent. This teaching does not anticipate claim 1 of the present application at least because the radioactive sleeve 7 of Park et al. is not formed into a coil.

The Examiner then takes the position that it would have been obvious to make the Tam et al. radioactive portion 312 as a separate member which is later attached to the stent so that it would have the advantage of providing a more versatile combination of parts. The applicant disagrees with this conclusion.

First, the applicant does not see how a more versatile combination of parts can be achieved in the context of Tam et al. by replacing a coating with a separate sheet to be attached

to the stent. Specifically, the Tam et al. stent is in the form of a coil which must be capable of radial expansion to accomplish its purpose. Thus, the provision of a separate sheet including radioactive material does not provide additional versatility since this separate sheet must still be attached to the stent in a manner which allows the Tam et al. stent to radially expand by uncoiling. Thus, due to the constraints posed by the stent of Tam et al. having to function in a certain way, there is no additional versatility provided by use of a separate sheet since both of the references still require that the separate sheet to be attached to the stent prior to delivery to the body.

Second, even if there were a reason to make the coating 312 of radioactive material Tam et al. from a separate sheet as in Park et al., and subsequently attach it to the substrate, a skilled person would follow the teaching of Park et al. to provide a sleeve 7 of radioactive material rather than a coiled sheet as is required by the present claims. One reason for this is that Park et al. desires to evenly disperse the radioactive dose over the surface of the stent. Park et al. solves this problem by providing a cylindrical sleeve.

A second reason why a skilled person following the teachings of Park et al. would not contemplate forming a separate coiled sheet is that Park et al. teaches that the sleeve 7 should be made by inserting the stent into a glass tube and forming the sleeve by pouring a solution of radioactive material into the glass tube, evaporating the solvent and then carefully removing the radioactive sleeve from the inner wall of the glass tube. This manufacturing process would not be suitable for forming a coiled sheet since a very complex glass device would be required and it would be very difficult to separate a coiled sheet from the glass device, even if it were possible to evenly distribute radioactive material over the glass device using a solvent evaporation method.

A third reason why a skilled person would not arrive at the present invention following Park et al. is that Park et al. contemplates a second embodiment wherein non-radioactive material is adhered to the stent and subsequently bombarded with neutrons to activate it. Forming the non-radioactive material into a coil prior to bombardment with neutrons would make it practically impossible to evenly activate the non-radioactive material by neutron bombardment since material on the outer surface of the coil would receive far more neutron bombardment than material within the coil. For these reasons, it is requested that the rejection of claims 1-9, 11-12 and 20-25, under 35 U.S.C. 103(a) over Tam et al. in view of Park et al. be withdrawn.

Accordingly, favorable consideration, entry of the amendments and issuance of a Notice of Allowance are requested.

Respectfully submitted,

4/5/2004

Kevin J. Dunleavy
Registration No. 32,024

Customer No. 21302
KNOBLE & YOSHIDA
Eight Penn Center
Suite 1350
1628 John F. Kennedy Blvd.
Philadelphia, PA 19103
Telephone: (215) 599-0600
Facsimile: (215) 599-0601
Email: KJDunleavy@patentwise.com